IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant	: Marie-Christine ETIENNE	Confirmation No: 2300
Appl. No.	: 09/839,366	
Filed	: April 23, 2001	
Title	: HOMEOPATHIC COMPOSITIONS FOR THE TREATMENT OF VIRAL AND METABOLIC DISEASES	
TC/A.U.	: 1617	
Examiner	: R. Travers	
Docket No.:	: ETIE3001/REF	
Customer No:	: 23364	

BRIEF ON APPEAL

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

This brief on appeal is submitted in triplicate with the required appeal fee. The date for filing the appeal brief has been extended to expire on February 15, 2004, by the filing herewith of a petition for a one month extension of time and payment of the required fee.

I. REAL PARTY IN INTEREST

The real party in interest is Dr. Marie-Christine ETIENNE.

II. RELATED APPEALS AND INTERFERENCES

There are no related appeals or interferences with respect to the claimed invention which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal known to appellant, or appellants' legal representative.

III. STATUS OF THE CLAIMS

This application contains 22 claims. Claims 1-22 have been finally rejected and are the claims on appeal. No claims have been canceled from the application.

IV. STATUS OF AMENDMENTS AFTER FINAL REJECTION

No amendment after final rejection was filed.

V. SUMMARY OF INVENTION

The present invention concerns the use of a homeopathic product for the preparation of a medicament intended to bring about the elimination from the cells which contain it a compound that is identical in nature to the active principle in the specific case in which the elimination result in restoring the normal operation of the pericellular transport systems which are disturbed. (Page 1, lines 15-20.)

The present invention relates the use of a homeopathic product for the preparation of a drug intended for treating metabolic diseases. (Page 1, lines 21-22.)

The general formula of the homeopathic product is RxCH. (Page 1, line 23.)

The metabolic diseases to which the invention relates are diseases characterized by the intracellular accumulation or intracellular deficit of a chemical substance of simple or complex formula , which can vary from case to case and is designated here by R. (Page 2, lines 1-4.)

In fact, R acts on the pericellular transport systems with respect to itself, which systems have broken down and to which it restores correct function. These diseases are frequently referred to as genetic in the prior art . (Page 2, lines 5-7.)

The xCH dilutions are defined as follows: 15 to 30 CH for diseases caused by intracellular retention. 4CH, 5CH 7CH, 9CH for diseases caused by an intracellular deficit. (Page 2, lines 8-10.)

For some of these metabolic diseases, the pathological manifestations are the direct consequence of the intracellular accumulation or intracellular deficit of a chemical substance. For others (of these diseases) the relationship with the intracellular deficit or excess is very indirect : The consequence of this excess or deficit is the production by the cell of abnormal substances responsible for the observed pathological manifestations. These substances have a structure possessing anomalies which are due to the abnormal conditions in which the cell functions. The cells start to produce antibodies of abnormal structure which are responsible for allergies or, in the case of autoantibodies responsible for autoimmune diseases. Thus secondary to the anomalies of the transport systems, the cells start to produce all kinds of chemicals of abnormal structure or in abnormal amounts which are responsible for a very wide variety of complaints such as hypertension in the case of an overproduction of aldosterone gout in the case of an overproduction of uric acid. (Page 2, lines 11-24.)

The invention assert that all diseases caused by the intracellular deficit or excess of a chemical substance, and qualified in the prior art as genetic, are due to dysfunctions of pericellular transport systems with respect to the chemical substance which is in excess or deficit inside the cells. (Page 2, lines 25-28.)

The invention, which is based on these novel and original theories is based on the use of the property of elimination of chemical substances from the cell and from the

organism under the influence of their homeopathic dilution in order to restore normal function to the perturbed pericellular transport systems with respect to these chemical substances. In the invention, the ion channels and pericellular transport systems function along concentration gradients which cause the ions and other substances to pass from the more concentrated medium to the less concentrated medium. (Page 1, lines 1-5.)

VI. ISSUES

The rejection of claims 1-22 under 35 U.S.C. 101 because the claimed invention, setting forth an incredible utility, lacks patentable utility is one issue on appeal.

The rejection of claims 1-11, 13-19 and 20-22 under 35 U.S.C. 112, first paragraph, is an issue on appeal of which the corollary objection is also an issue.

The rejection of claims 1-11, 13-19 and 20-22 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the invention is a further issue on appeal.

The rejection of claims 1-22 under 35 U.S.C. 103 as being unpatentable over Labrecque et al., Tetau and Applicant's admission on the record is an issue on appeal.

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VII. GROUPING OF THE CLAIMS

The claims as grouped in the Final Rejection do not stand or fall together.

VIII. ARGUMENT

The Rejection Under 35 USC 101 Should Be Reversed

The rejection of claims 1-22 under 35 U.S.C. 101 because the claimed invention, setting forth an incredible utility, lacks patentable utility should be reversed. It is urged in the Official Action that Applicant has supplied only anecdotal evidence for the claimed subject matter. However, evidence has been provided! The Examiner refers to two prior art references which is urged employs the same manner of therapy. This is specifically traversed in view of the results achieved by the presently claimed invention and as described in the working examples in the present specification. It is not believed that this is sufficient evidence to rebut the initial presumption that Applicant's statements with respect to utility are true. While Applicant appreciates the Examiner's comments that one of ordinary skill in the art would view a randomized, double-blind, placebo-controlled clinical trial more convincing then anecdotal accounts related by Applicant, this is not the standard for a lack of utility rejection under 35 U.S.C. 101. There is no case law which

supports this requirement. This is especially true for the claims directed to method of eliminating an active principle from cells of a mammal. This is in no way an incredible utility. It does not call for a cure or prevention, but is to a method of elimination.

In this regard, Applicant notes that the corresponding PCT application has issued as European patent number 0655928 on December 29, 1997, and this is at least as credible evidence in support of the utility of the present invention as utility is an issue of patentability for a European Patent as it is for a United States patent. Moreover, the reliance on prior art to reject the claim subject matter is clear evidence that the claimed utility is not incredible. These references clearly establish that the utility of the claimed invention is not incredible requiring a higher degree of proof than normal. Moreover, the present application contains experimentation described in Applicant's specification which establishes the utility of the claimed subject matter. See for example some clinical observation of cases of patients treated with compounds RxCH belonging a medicament of the invention beginning on page 10 of Applicant's specification. As noted by the Examiner, the application contains clinical evidence as set forth in the Examples which provide effective results for the presently claimed invention. Moreover, the French patent which corresponds to the present application's parent has issued as a patent further evidencing that individuals of skill in the art would appreciate that the claimed invention does not have an incredible utility requiring the submission of double-blind tests.

As a final note, claim 12 is not included in the rejection of the claims under the first paragraph of 35 USC 112 and therefore, claim 12 must comply with 35 USC 101. The impropriety of the rejection under 35 U.S.C. 101 has been established and this rejection should be reversed on appeal.

The Objection Under 35 USC 112, first paragraph, Should Be withdrawn

Applicant notes the objection to the specification under 35 U.S.C. 112, first paragraph, as failing to adequately teach how to make and use the invention and thereby failing to provide an enabling disclosure. Applicant has noted the *In re Wands*

Decision and believe that the present specification complies with the requirements of this Decision as would be appreciated by one of ordinary skill in the art. The present application contains a detailed discussion of the invention along with working Examples including studies by Applicant in the clinic. Clearly, based upon the disclosure of the specific types of treatments employed, including the concentration and the active ingredient treated, one of ordinary skill in the art would clearly be able to perform the invention without undue experimentation.

Applicant has carefully considered the rejection of claims 1-11, 13-19 and 20-22 under 35 U.S.C. 112, first paragraph, for the reasons set forth in the objection to the specification. It is noted that this rejection does not apply to claim 12 which has not been rejected under 35 U.S.C. 112. Claim 12 deals with the method of claim 1 wherein the active principle to be eliminated is a virus or a viral particle. Thus, the specification is fully enabling by the Examiner's admission, at least with respect to the viral subject matter of claim 12. Accordingly, it is most respectfully requested that the objection to the specification be withdrawn.

The First Paragraph Rejection Under 35 USC 112 Should Be Reversed

Applicant has carefully considered the rejection of claims 1-11, 13-19 and 20-22 under 35 U.S.C. 112, first paragraph, for the reasons set forth in the objection to the specification. It is noted that this rejection does not apply to claim 12 which **has not been** rejected under 35 U.S.C. 112. Claim 12 deals with the method of claim 1 wherein the active principle to be eliminated is a virus or a viral particle. Thus, the specification is fully enabling in this regard.

Applicant most respectfully submits that for similar reasons the specification is fully enabling for all of the claims in the application. Applicant notes that the independent claims are further restricted and the scope of the claims must be taken into consideration in evaluating the deficiency of the disclosure. The metabolic diseases to which the invention relates are diseases characterized by the intracellular accumulation or

intracellular deficit of a chemical substance of simple or complex formula , which can vary from case to case and is designated in the specification by R. In fact, R acts on the pericellular transport systems with respect to itself, which systems have broken down and to which it restores correct function. These diseases are frequently referred to as genetic in the prior art .

The invention assert that all diseases caused by the intracellular deficit or excess of a chemical substance, and qualified in the prior art as genetic, are due to dysfunctions of pericellular transport systems with respect to the chemical substance which is in excess or deficit inside the cells.

The invention, which is based on these novel and original theories is based on the use of the property of elimination of chemical substances from the cell and from the organism under the influence of their homeopathic dilution in order to restore normal function to the perturbed pericellular transport systems with respect to these chemical substances. In the invention, the ion channels and pericellular transport systems function along concentration gradients which cause the ions and other substances to pass from the more concentrated medium to the less concentrated medium. According to the laws of osmosis, water follows the particles and it is the medium containing the larger number of molecules which becomes the less concentrated medium, so the transport systems become blocked in the direction of entry into the cell if the cell already contains an excess of the chemical substance in question, or in the direction of exit from the cell if the cell already contains a deficit of the chemical substance in question.

In the invention, in the case of diseases caused by intracellular retention, for example of minerals, water passes into the cells, where the minerals are already present in large amounts, and reduces the concentration inside the cell, where there is the greatest amount of minerals. (Minerals are taken as a non-limiting example, but it is possible to have intracellular retention of other products of various chemical types.) The minerals therefore have an indefinite tendency to accumulate inside the cell, where they are already in excess. The property of elimination of intracellular components from the cell and from the organism under the influence of their homeopathic dilution is

immediately applicable to this type of complaint. The homeopathic dilution of the component in excess causes the component (or whatever the chemical substance may be) which is in excess to leave the cells, reducing the intracellular overloading. However, there is another mechanism to explain an action on the pericellular transport systems: the administration of the homeopathic dilution of the product which is in excess in the cell also causes water to be drawn around the eliminated molecules, since water follows the minerals and other products and leaves the cell. The extracellular medium becomes punctually less concentrated than the intracellular medium. The pericellular transport systems corresponding to this point, which are regulated along a concentration gradient, i.e. some of the entrance doors swing to expel from the cell the product which could only enter it. The consequences of these punctual and repeated eliminations of a few molecules are a long-term restoration of normal function to the transport systems under the influence of the repeated administration of the homeopathic remedy in question over weeks, months and years.

For example, claim 2 further specifies that the effect of the elimination of a mineral compound is to restore normal function to an ion channel. The specific dilutions used in the method are claimed in claim 9. The principle to be eliminated in 10 is specified as mineral compound and the location is the restoration of the normal function to the ion channel. Moreover, claim 19 provides that the mineral compound is a potassium, calcium or antimony containing mineral compound as does claim 20. Further, claim 20 is further specific in defining the value of x as 4, 5, 7, 15 or 30. Turning to the working examples set forth in the present application, see pages 10 through 15, it may be seen that one of ordinary skill in the art would certainly find the specification enabling with no more than routine experimentation. Accordingly, it is most respectfully requested that this rejection be reversed on appeal.

The Rejection Under 35 USC 112, Second Paragraph, Should be Reversed.

The rejection of claims 1-11, 13-19 and 20-22 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the invention has been carefully considered. Applicant again notes that claim 12 is not included in this rejection and therefore claim 12 is in full compliance with 35 U.S.C. 112.

The Examiner urges that the claims are indefinite by the phrase "active principle, R" or, those compounds that are poisons or part of a poison and thereby failing to clearly set forth the metes and bounds of the patent protection desired. However, Applicant refers to the prior art relied upon by the Examiner in the prior art rejection and also the level of skill of one of ordinary skill in the art to which the invention pertains and the working examples in applicant's specification. The clear meaning of the term is discernible to one of ordinary skill in the art, especially from a reading of the specification and the working examples contained therein. The active principle would be understood to mean that material or compound which is causing the disturbance in the system. For example, the absence of black antimony sulfide is noted in case No. 3 on pages 14 and 15. This would be an active principle as would be understood by one of ordinary skill in the art to which the invention pertains.

Moreover, the terms referred to in the rejection only appear in the main claims and the further limited claims do not seem to have been taken into consideration in the rejection as this would be fully understood by the skill artisan. Compounds which are poisons or parts of poisons would be known to one of ordinary skill in the art to which the invention pertains. Poisons are well know materials which have a poisonous effect on mammals. Again, one of ordinary skill in the art would have no trouble understanding the meaning of this term by looking to a dictionary which defines the term as a substance which through its chemical action kills or injures a mammal. It is not necessary to discover the substance which is the poison but to use the substance in the process of the present invention. Accordingly, it is most respectfully requested that the Board reverses this rejection.

The Rejection of Claims 1-22 Under 35 U.S.C. 103 As Being Unpatentable Over Labrecque et al., Tetau And Applicant's Admission Should Be Reversed.

The rejection of claims 1-22 under 35 U.S.C. 103 as being unpatentable over Labrecque et al., Tetau and Applicant's admission on the record is not sustainable. Applicant has not received a copy of the references which were cited in the parent application and it is believed that none of these are of record in the present application.

Applicant wishes to direct the Examiner's attention to the basic requirements of a prima facie case of obviousness as set forth in the MPEP § 2143. This section states that to establish a prima facie case of obviousness, three basic criteria first must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine the reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations.

The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, not in applicant's disclosure. In re Vaeck, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991).

Section 2143.03 states that all claim limitations must be taught or suggested by the prior art. In re Royka, 490 F.2d 981, 180 USPQ 580 (CCPA 1974). "All words in a claim must be considered in judging the patentability of that claim against the prior art." In re Wilson, 424 F.2d 1382, 1385, 165 USPQ 494, 496 (CCPA 1970). If an independent claim is nonobvious under 35 U.S.C. 103, then any claim depending therefrom is nonobvious. In re Fine, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988).

Applicants also most respectfully direct the Examiner's attention to MPEP § 2144.08 (page 2100-114) wherein it is stated that Office personnel <u>should consider all rebuttal argument and evidence present by applicant and the citation of In re Soni for error in not considering evidence presented in the specification</u>.

It is urged in the Official Action that claims 1-22 and the primary reference differ as to the metal ion employed and the proposed mechanism by which the homeopathic therapy effected the desired therapeutic regime. Applicant most respectfully submits that Labrecque does not treat anything. People who develop plantar warts are people who have one particular pericellular transport system which is deficient. If such a person is treated with the one homeopathic compound which is able to restore normal function to his one perturbed pericellular transport system, his plantar warts disappear. The compounds which are able to treat plantar warts are antimonium crudum, nitric acid, thuya, causticum, magnesia muriatica, and graphites. Labrecque attempts to treat plantar warts using three homeopathic compounds taken together, and the only result was aggravation of the warts. Labrecque makes no mention of the treatment of genetic diseases.

The first deficiency is said to be cured by Tetau teaching employment of divalent metal ions to effect the desired therapeutic goals. However, there is no specificity in the Official action as to where in Tetau these teachings are present and to which divalent metal ions in the claims as applied. For example, where is there any teaching concerning restoration of normal function to the perturbed pericellular transport system as required by claim 1? Similarly, where is the teaching with respect to the specific dilutions set forth in claims 9, 11 and 18? These are specific claim limitations which cannot be ignored. Applicant wishes to emphasize that obvious to try is not the standard of obviousness under 35 U.S.C. 103 and that Applicant's specification may not be used as a teaching reference to provide the necessary motivation to modify the prior art and arrive at the claimed invention. In re Fritch, 23 USPQ 1780, 1784(Fed Cir. 1992) ("It is impermissible to engage in hindsight reconstruction of the claimed invention, using the applicant's structure as a template and selecting elements from references to fill the gaps.). Accordingly, it is most respectfully requested that this rejection be reversed on appeal.

The Rejection Of Claims 1-22 Under 35 U.S.C. 103 As Being Unpatentable Over Cazin et al., Besnouin and Applicant's Admission Should Be Reversed On Appeal.

The rejection of claims 1-22 under 35 U.S.C. 103 as being unpatentable over Cazin et al., Besnouin and Applicant's admission of record has been carefully considered but also should be reversed on appeal. The Official Action urges that Cazin et al. and Besnouin teach the homeopathic compounds herein claimed in combination with various pharmaceutical carriers and excipients in a dosage form, specifically arsenic compounds. It is further urged that these medicaments are taught as useful for producing the retention of, or causing excretion of compounds responsible for disease. It is then urged in the Official Action that the skilled artisan would have expected compounds residing in the same chemical period to possess therapeutically equivalent effects. However, there is no support in the Official Action to establish this equivalency. This statement is specifically traversed. Therefore, this aspect of the rejection is most respectfully traversed and in no way establishes a prima facie case of obviousness of the claims on appeal.

The second deficiency is said to be cured by Applicant's admission that the xCH factor effects the therapy in a similar and predictable manner but this is based upon Applicant's teaching which is not available as prior art and a rejection based upon such disclosure should be withdrawn. In re Fritch, 23 USPQ 1780, 1784(Fed Cir. 1992) ("It is impermissible to engage in hindsight reconstruction of the claimed invention, using the applicant's structure as a template and selecting elements from references to fill the gaps.).

It is then urged that the skilled artisan possessing the "Hahnemannian homeopathic dilution (xCH)", or "Korsakowian homeopathic dilution (xCH)" would possess the knowledge to effect the required therapy, and be motivated to apply such therapy regardless of etiology. Clearly, this is based upon the teachings in Applicant's specification which may not be used as a teaching reference to provide the missing motivation to modify the prior art to overcome the deficiencies in the prior art. Otherwise,

the rejection applies an obvious to try standard which is not the standard of obviousness under 35 USC 103.

Moreover, it is important to understand that diseases due to anomalies in the function of pericellular transport systems are the subject of the claims on appeal. In a homeopathic product of the formula RxCH, in which R is the active principle and in which xCH is a homeopathic dilution of said active ingredient R to eliminate R from the cells **to restore normal function to the perturbed pericellular transport systems**. This is a claim limitation which cannot be ignored.

This is characterized more specifically in claim 2 in that the compound to be eliminated is a mineral compound and that the effect of its elimination is to restore normal function to an ion channel. This claim feature is not suggested by the prior art relied upon in the rejection and is not obvious from the combined teachings of the references. The presently claimed invention consists of using the property of elimination of intracellular elements from the cell under the influence of their homeopathic dilution to re-establish normal function of the disturbed pericellular transport systems is not suggested in the prior art.

The claims on appeal consist of the medical application of a further property of homeopathic dilutions which is causing the elimination from the cell and from the organism of intracellular chemical as a result of their homeopathic dilution and using this elimination property to re-establish normal function of the disturbed pericellular transport system. As a result of the novel and unobvious conclusion reached by Applicant to arrive at a novel theory of the function of pericellular transport systems based on concentration gradients, the claimed invention is clearly unobvious to one of ordinary skill in the art. Accordingly, it is most respectfully requested that this rejection be withdrawn or reversed by the Board of Appeals.

IX. CONCLUSION

In view of the above arguments, the rejections of the claims on appeal should not be sustained. The Final Rejection should be reversed and the application passed to issue.

Respectfully submitted,

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February 17, 2004

APPENDIX

CLAIMS ON APPEAL

1. A method for causing the elimination of an active principle, R, from cells of a mammal which contain the active principle, R, which comprises administering to said mammal, a compound identical in nature to said active principle in a homeopathic product of the formula RxCH, in which R is the active principle and in which xCH is a homeopathic dilution of said active ingredient R to eliminate R from the cells to restore normal function to the perturbed pericellular transport systems.

2. The method of claim 1, characterized in that the compound to be eliminated is a mineral compound and that the effect of its elimination is to restore normal function to an ion channel.

3. The method of claim 1, characterized in that the compound to be eliminated is a poison or part of a poison.

4. The method according to claim 1 which is for treating diseases caused by a metabolic error consisting either of an intracellular accumulation of a compound of simple or complex formula, or of an intracellular deficit of such a compound.

5. The method according to claim 4, characterized in that the consequence of the metabolic error is the production of abnormal metabolites, especially abnormal antibodies such as autoantibodies.

6. The method according to claim 4, characterized in that the metabolic error is genetically determined.

7. The method according to claim 5, characterized in that the metabolic error is genetically determined.

8. The method of claim 1, wherein xCH is hahnemannian or korsakowian homeopathic dilution.

9. The method of claim 1, wherein x is 4, 5, 7, 15 or 30.

10. The method of claim 9, wherein the active principle to be eliminated is a mineral compound and normal function is restored to an ion channel.

11. The method of claim 10, wherein x is 4, 5, 7, 15 or 30 and the active principle to be eliminated is a poison or part of a poison.

12. The method of claim 1, wherein the active principle to be eliminated is a virus or a viral particle.

13. A method of treating a disease caused by metabolic error consisting either or an intracellular accumulation of a compound of simple or complex formula, or of an intracellular deficit of such a compound which comprises administering to cells containing such a compound R or in need of said compound R, a homeopathic product having a formula RxCH in which R is said compound and in which xCH is its homeopathic dilution to treat said disease caused by metabolic error consisting either of an intracellular accumulation of said compound of simple or complex formula, or of an intracellular deficit of such a compound.

14. The method of claim 13, characterized in that the consequence of the metabolic error is the production of abnormal metabolites.

15. The method of claim 14, wherein the abnormal metabolites are abnormal antibodies.

16. The method of claim 15, wherein the abnormal antibodies are autoantibodies.

17. The method of claim 16, wherein the metabolic error is genetically determined.

18. The method of claim 16, wherein x is 4, 5, 7, 15 or 30.

19. The method of claim 2, wherein the mineral compound is a potassium, calcium or antimony containing mineral compound.

20(Amended). The method of claim 2, wherein R is a mineral compound which is a potassium, calcium or antimony containing mineral compound, and x is 4, 5, 7, 15 or 30.

21. Application of homeopathic compounds of the general formula RxCH to the elimination of an intracellular chemical substance R from the cell, when this elimination causes the restoration of normal function to the perturbed pericellular transport systems, in order to obtain drugs which, by causing this elimination from the cell are intended for restoring normal function to the perturbed pericellular transport systems.

22. The application of claim 21, wherein xCH is hahnemannian or korsakowian homeopathic dilution, R is a mineral compound which is a potassium, calcium or antimony containing mineral compound and wherein x is 4, 5, 7, 15 or 30.

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For some of these metabolic diseases, the pathological manifestations are the direct consequence of the intracellular accumulation or intracellular deficit of a chemical substance. For others (of these diseases) the relationship with the intracellular deficit or excess is very indirect : The consequence of this excess or deficit is the production by the cell of abnormal substances responsible for the observed pathological manifestations. These substances have a structure possessing anomalies which are due to the abnormal conditions in which the cell functions. The cells start to produce antibodies of abnormal structure which are responsible for allergies or, in the case of autoantibodies responsible for autoimmune diseases. Thus secondary to the anomalies of the transport systems, the cells start to produce all kinds of chemicals of abnormal structure or in abnormal amounts which are responsible for a very wide variety of complaints such as hypertension in the case of an overproduction of aldosterone gout in the case of an overproduction of uric acid. (Page 2, lines 11-24.)

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The rejection of claims 1-22 under 35 U.S.C. 101 because the claimed invention, setting forth an incredible utility, lacks patentable utility should be reversed. It is urged in the Official Action that Applicant has supplied only anecdotal evidence for the claimed subject matter. However, evidence has been provided! The Examiner refers to two prior art references which is urged employs the same manner of therapy. This is specifically traversed in view of the results achieved by the presently claimed invention and as described in the working examples in the present specification. It is not believed that this is sufficient evidence to rebut the initial presumption that Applicant's statements with respect to utility are true. While Applicant appreciates the Examiner's comments that one of ordinary skill in the art would view a randomized, double-blind, placebo-controlled clinical trial more convincing then anecdotal accounts related by Applicant, this is not the standard for a lack of utility rejection under 35 U.S.C. 101. There is no case law which

supports this requirement. This is especially true for the claims directed to method of eliminating an active principle from cells of a mammal. This is in no way an incredible utility. It does not call for a cure or prevention, but is to a method of elimination.

In this regard, Applicant notes that the corresponding PCT application has issued as European patent number 0655928 on December 29, 1997, and this is at least as credible evidence in support of the utility of the present invention as utility is an issue of patentability for a European Patent as it is for a United States patent. Moreover, the reliance on prior art to reject the claim subject matter is clear evidence that the claimed utility is not incredible. These references clearly establish that the utility of the claimed invention is not incredible requiring a higher degree of proof than normal. Moreover, the present application contains experimentation described in Applicant's specification which establishes the utility of the claimed subject matter. See for example some clinical observation of cases of patients treated with compounds RxCH belonging a medicament of the invention beginning on page 10 of Applicant's specification. As noted by the Examiner, the application contains clinical evidence as set forth in the Examples which provide effective results for the presently claimed invention. Moreover, the French patent which corresponds to the present application's parent has issued as a patent further evidencing that individuals of skill in the art would appreciate that the claimed invention does not have an incredible utility requiring the submission of double-blind tests.

As a final note, claim 12 is not included in the rejection of the claims under the first paragraph of 35 USC 112 and therefore, claim 12 must comply with 35 USC 101. The impropriety of the rejection under 35 U.S.C. 101 has been established and this rejection should be reversed on appeal.

The Objection Under 35 USC 112, first paragraph, Should Be withdrawn

Applicant notes the objection to the specification under 35 U.S.C. 112, first paragraph, as failing to adequately teach how to make and use the invention and thereby failing to provide an enabling disclosure. Applicant has noted the *In re Wands*

Decision and believe that the present specification complies with the requirements of this Decision as would be appreciated by one of ordinary skill in the art. The present application contains a detailed discussion of the invention along with working Examples including studies by Applicant in the clinic. Clearly, based upon the disclosure of the specific types of treatments employed, including the concentration and the active ingredient treated, one of ordinary skill in the art would clearly be able to perform the invention without undue experimentation.

Applicant has carefully considered the rejection of claims 1-11, 13-19 and 20-22 under 35 U.S.C. 112, first paragraph, for the reasons set forth in the objection to the specification. It is noted that this rejection does not apply to claim 12 which has not been rejected under 35 U.S.C. 112. Claim 12 deals with the method of claim 1 wherein the active principle to be eliminated is a virus or a viral particle. Thus, the specification is fully enabling by the Examiner's admission, at least with respect to the viral subject matter of claim 12. Accordingly, it is most respectfully requested that the objection to the specification be withdrawn.

The First Paragraph Rejection Under 35 USC 112 Should Be Reversed

Applicant has carefully considered the rejection of claims 1-11, 13-19 and 20-22 under 35 U.S.C. 112, first paragraph, for the reasons set forth in the objection to the specification. It is noted that this rejection does not apply to claim 12 which **has not been** rejected under 35 U.S.C. 112. Claim 12 deals with the method of claim 1 wherein the active principle to be eliminated is a virus or a viral particle. Thus, the specification is fully enabling in this regard.

Applicant most respectfully submits that for similar reasons the specification is fully enabling for all of the claims in the application. Applicant notes that the independent claims are further restricted and the scope of the claims must be taken into consideration in evaluating the deficiency of the disclosure. The metabolic diseases to which the invention relates are diseases characterized by the intracellular accumulation or

intracellular deficit of a chemical substance of simple or complex formula , which can vary from case to case and is designated in the specification by R. In fact, R acts on the pericellular transport systems with respect to itself, which systems have broken down and to which it restores correct function. These diseases are frequently referred to as genetic in the prior art .

The invention assert that all diseases caused by the intracellular deficit or excess of a chemical substance, and qualified in the prior art as genetic, are due to dysfunctions of pericellular transport systems with respect to the chemical substance which is in excess or deficit inside the cells.

The invention, which is based on these novel and original theories is based on the use of the property of elimination of chemical substances from the cell and from the organism under the influence of their homeopathic dilution in order to restore normal function to the perturbed pericellular transport systems with respect to these chemical substances. In the invention, the ion channels and pericellular transport systems function along concentration gradients which cause the ions and other substances to pass from the more concentrated medium to the less concentrated medium. According to the laws of osmosis, water follows the particles and it is the medium containing the larger number of molecules which becomes the less concentrated medium, so the transport systems become blocked in the direction of entry into the cell if the cell already contains an excess of the chemical substance in question, or in the direction of exit from the cell if the cell already contains a deficit of the chemical substance in question.

In the invention, in the case of diseases caused by intracellular retention, for example of minerals, water passes into the cells, where the minerals are already present in large amounts, and reduces the concentration inside the cell, where there is the greatest amount of minerals. (Minerals are taken as a non-limiting example, but it is possible to have intracellular retention of other products of various chemical types.) The minerals therefore have an indefinite tendency to accumulate inside the cell, where they are already in excess. The property of elimination of intracellular components from the cell and from the organism under the influence of their homeopathic dilution is

immediately applicable to this type of complaint. The homeopathic dilution of the component in excess causes the component (or whatever the chemical substance may be) which is in excess to leave the cells, reducing the intracellular overloading. However, there is another mechanism to explain an action on the pericellular transport systems: the administration of the homeopathic dilution of the product which is in excess in the cell also causes water to be drawn around the eliminated molecules, since water follows the minerals and other products and leaves the cell. The extracellular medium becomes punctually less concentrated than the intracellular medium. The pericellular transport systems corresponding to this point, which are regulated along a concentration gradient, i.e. some of the entrance doors swing to expel from the cell the product which could only enter it. The consequences of these punctual and repeated eliminations of a few molecules are a long-term restoration of normal function to the transport systems under the influence of the repeated administration of the homeopathic remedy in question over weeks, months and years.

For example, claim 2 further specifies that the effect of the elimination of a mineral compound is to restore normal function to an ion channel. The specific dilutions used in the method are claimed in claim 9. The principle to be eliminated in 10 is specified as mineral compound and the location is the restoration of the normal function to the ion channel. Moreover, claim 19 provides that the mineral compound is a potassium, calcium or antimony containing mineral compound as does claim 20. Further, claim 20 is further specific in defining the value of x as 4, 5, 7, 15 or 30. Turning to the working examples set forth in the present application, see pages 10 through 15, it may be seen that one of ordinary skill in the art would certainly find the specification enabling with no more than routine experimentation. Accordingly, it is most respectfully requested that this rejection be reversed on appeal.

The Rejection Under 35 USC 112, Second Paragraph, Should be Reversed.

The rejection of claims 1-11, 13-19 and 20-22 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the invention has been carefully considered. Applicant again notes that claim 12 is not included in this rejection and therefore claim 12 is in full compliance with 35 U.S.C. 112.

The Examiner urges that the claims are indefinite by the phrase "active principle, R" or, those compounds that are poisons or part of a poison and thereby failing to clearly set forth the metes and bounds of the patent protection desired. However, Applicant refers to the prior art relied upon by the Examiner in the prior art rejection and also the level of skill of one of ordinary skill in the art to which the invention pertains and the working examples in applicant's specification. The clear meaning of the term is discernible to one of ordinary skill in the art, especially from a reading of the specification and the working examples contained therein. The active principle would be understood to mean that material or compound which is causing the disturbance in the system. For example, the absence of black antimony sulfide is noted in case No. 3 on pages 14 and 15. This would be an active principle as would be understood by one of ordinary skill in the art to which the invention pertains.

Moreover, the terms referred to in the rejection only appear in the main claims and the further limited claims do not seem to have been taken into consideration in the rejection as this would be fully understood by the skill artisan. Compounds which are poisons or parts of poisons would be known to one of ordinary skill in the art to which the invention pertains. Poisons are well know materials which have a poisonous effect on mammals. Again, one of ordinary skill in the art would have no trouble understanding the meaning of this term by looking to a dictionary which defines the term as a substance which through its chemical action kills or injures a mammal. It is not necessary to discover the substance which is the poison but to use the substance in the process of the present invention. Accordingly, it is most respectfully requested that the Board reverses this rejection.

The Rejection of Claims 1-22 Under 35 U.S.C. 103 As Being Unpatentable Over Labrecque et al., Tetau And Applicant's Admission Should Be Reversed.

The rejection of claims 1-22 under 35 U.S.C. 103 as being unpatentable over Labrecque et al., Tetau and Applicant's admission on the record is not sustainable. Applicant has not received a copy of the references which were cited in the parent application and it is believed that none of these are of record in the present application.

Applicant wishes to direct the Examiner's attention to the basic requirements of a prima facie case of obviousness as set forth in the MPEP § 2143. This section states that to establish a prima facie case of obviousness, three basic criteria first must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine the reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations.

The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, not in applicant's disclosure. In re Vaeck, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991).

Section 2143.03 states that all claim limitations must be taught or suggested by the prior art. In re Royka, 490 F.2d 981, 180 USPQ 580 (CCPA 1974). "All words in a claim must be considered in judging the patentability of that claim against the prior art." In re Wilson, 424 F.2d 1382, 1385, 165 USPQ 494, 496 (CCPA 1970). If an independent claim is nonobvious under 35 U.S.C. 103, then any claim depending therefrom is nonobvious. In re Fine, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988).

Applicants also most respectfully direct the Examiner's attention to MPEP § 2144.08 (page 2100-114) wherein it is stated that Office personnel should consider all rebuttal argument and evidence present by applicant and the citation of In re Soni for error in not considering evidence presented in the specification.

It is urged in the Official Action that claims 1-22 and the primary reference differ as to the metal ion employed and the proposed mechanism by which the homeopathic therapy effected the desired therapeutic regime. Applicant most respectfully submits that Labrecque does not treat anything. People who develop plantar warts are people who have one particular pericellular transport system which is deficient. If such a person is treated with the one homeopathic compound which is able to restore normal function to his one perturbed pericellular transport system, his plantar warts disappear. The compounds which are able to treat plantar warts are antimonium crudum, nitric acid, thuya, causticum, magnesia muriatica, and graphites. Labrecque attempts to treat plantar warts using three homeopathic compounds taken together, and the only result was aggravation of the warts. Labrecque makes no mention of the treatment of genetic diseases.

The first deficiency is said to be cured by Tetau teaching employment of divalent metal ions to effect the desired therapeutic goals. However, there is no specificity in the Official action as to where in Tetau these teachings are present and to which divalent metal ions in the claims as applied. For example, where is there any teaching concerning restoration of normal function to the perturbed pericellular transport system as required by claim 1? Similarly, where is the teaching with respect to the specific dilutions set forth in claims 9, 11 and 18? These are specific claim limitations which cannot be ignored. Applicant wishes to emphasize that obvious to try is not the standard of obviousness under 35 U.S.C. 103 and that Applicant's specification may not be used as a teaching reference to provide the necessary motivation to modify the prior art and arrive at the claimed invention. In re Fritch, 23 USPQ 1780, 1784(Fed Cir. 1992) ("It is impermissible to engage in hindsight reconstruction of the claimed invention, using the applicant's structure as a template and selecting elements from references to fill the gaps.). Accordingly, it is most respectfully requested that this rejection be reversed on appeal.

The Rejection Of Claims 1-22 Under 35 U.S.C. 103 As Being Unpatentable Over Cazin et al., Besnouin and Applicant's Admission Should Be Reversed On Appeal.

The rejection of claims 1-22 under 35 U.S.C. 103 as being unpatentable over Cazin et al., Besnouin and Applicant's admission of record has been carefully considered but also should be reversed on appeal. The Official Action urges that Cazin et al. and Besnouin teach the homeopathic compounds herein claimed in combination with various pharmaceutical carriers and excipients in a dosage form, specifically arsenic compounds. It is further urged that these medicaments are taught as useful for producing the retention of, or causing excretion of compounds responsible for disease. It is then urged in the Official Action that the skilled artisan would have expected compounds residing in the same chemical period to possess therapeutically equivalent effects. However, there is no support in the Official Action to establish this equivalency. This statement is specifically traversed. Therefore, this aspect of the rejection is most respectfully traversed and in no way establishes a prima facie case of obviousness of the claims on appeal.

The second deficiency is said to be cured by Applicant's admission that the xCH factor effects the therapy in a similar and predictable manner but this is based upon Applicant's teaching which is not available as prior art and a rejection based upon such disclosure should be withdrawn. In re Fritch, 23 USPQ 1780, 1784(Fed Cir. 1992) ("It is impermissible to engage in hindsight reconstruction of the claimed invention, using the applicant's structure as a template and selecting elements from references to fill the gaps.).

It is then urged that the skilled artisan possessing the "Hahnemannian homeopathic dilution (xCH)", or "Korsakowian homeopathic dilution (xCH)" would possess the knowledge to effect the required therapy, and be motivated to apply such therapy regardless of etiology. Clearly, this is based upon the teachings in Applicant's specification which may not be used as a teaching reference to provide the missing motivation to modify the prior art to overcome the deficiencies in the prior art. Otherwise,

the rejection applies an obvious to try standard which is not the standard of obviousness under 35 USC 103.

Moreover, it is important to understand that diseases due to anomalies in the function of pericellular transport systems are the subject of the claims on appeal. In a homeopathic product of the formula RxCH, in which R is the active principle and in which xCH is a homeopathic dilution of said active ingredient R to eliminate R from the cells **to restore normal function to the perturbed pericellular transport systems**. This is a claim limitation which cannot be ignored.

This is characterized more specifically in claim 2 in that the compound to be eliminated is a mineral compound and that the effect of its elimination is to restore normal function to an ion channel. This claim feature is not suggested by the prior art relied upon in the rejection and is not obvious from the combined teachings of the references. The presently claimed invention consists of using the property of elimination of intracellular elements from the cell under the influence of their homeopathic dilution to re-establish normal function of the disturbed pericellular transport systems is not suggested in the prior art.

The claims on appeal consist of the medical application of a further property of homeopathic dilutions which is causing the elimination from the cell and from the organism of intracellular chemical as a result of their homeopathic dilution and using this elimination property to re-establish normal function of the disturbed pericellular transport system. As a result of the novel and unobvious conclusion reached by Applicant to arrive at a novel theory of the function of pericellular transport systems based on concentration gradients, the claimed invention is clearly unobvious to one of ordinary skill in the art. Accordingly, it is most respectfully requested that this rejection be withdrawn or reversed by the Board of Appeals.

IX. CONCLUSION

In view of the above arguments, the rejections of the claims on appeal should not be sustained. The Final Rejection should be reversed and the application passed to issue.

Respectfully submitted,

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APPENDIX

CLAIMS ON APPEAL

1. A method for causing the elimination of an active principle, R, from cells of a mammal which contain the active principle, R, which comprises administering to said mammal, a compound identical in nature to said active principle in a homeopathic product of the formula RxCH, in which R is the active principle and in which xCH is a homeopathic dilution of said active ingredient R to eliminate R from the cells to restore normal function to the perturbed pericellular transport systems.

2. The method of claim 1, characterized in that the compound to be eliminated is a mineral compound and that the effect of its elimination is to restore normal function to an ion channel.

3. The method of claim 1, characterized in that the compound to be eliminated is a poison or part of a poison.

4. The method according to claim 1 which is for treating diseases caused by a metabolic error consisting either of an intracellular accumulation of a compound of simple or complex formula, or of an intracellular deficit of such a compound.

5. The method according to claim 4, characterized in that the consequence of the metabolic error is the production of abnormal metabolites, especially abnormal antibodies such as autoantibodies.

6. The method according to claim 4, characterized in that the metabolic error is genetically determined.

7. The method according to claim 5, characterized in that the metabolic error is genetically determined.

8. The method of claim 1, wherein xCH is hahnemannian or korsakowian homeopathic dilution.

9. The method of claim 1, wherein x is 4, 5, 7, 15 or 30.

10. The method of claim 9, wherein the active principle to be eliminated is a mineral compound and normal function is restored to an ion channel.

11. The method of claim 10, wherein x is 4, 5, 7, 15 or 30 and the active principle to be eliminated is a poison or part of a poison.

12. The method of claim 1, wherein the active principle to be eliminated is a virus or a viral particle.

13. A method of treating a disease caused by metabolic error consisting either or an intracellular accumulation of a compound of simple or complex formula, or of an intracellular deficit of such a compound which comprises administering to cells containing such a compound R or in need of said compound R, a homeopathic product having a formula RxCH in which R is said compound and in which xCH is its homeopathic dilution to treat said disease caused by metabolic error consisting either of an intracellular accumulation of said compound of simple or complex formula, or of an intracellular deficit of such a compound.

14. The method of claim 13, characterized in that the consequence of the metabolic error is the production of abnormal metabolites.

15. The method of claim 14, wherein the abnormal metabolites are abnormal antibodies.

16. The method of claim 15, wherein the abnormal antibodies are autoantibodies.

17. The method of claim 16, wherein the metabolic error is genetically determined.

18. The method of claim 16, wherein x is 4, 5, 7, 15 or 30.

19. The method of claim 2, wherein the mineral compound is a potassium, calcium or antimony containing mineral compound.

20(Amended). The method of claim 2, wherein R is a mineral compound which is a potassium, calcium or antimony containing mineral compound, and x is 4, 5, 7, 15 or 30.

21. Application of homeopathic compounds of the general formula RxCH to the elimination of an intracellular chemical substance R from the cell, when this elimination causes the restoration of normal function to the perturbed pericellular transport systems, in order to obtain drugs which, by causing this elimination from the cell are intended for restoring normal function to the perturbed pericellular transport systems.

22. The application of claim 21, wherein xCH is hahnemannian or korsakowian homeopathic dilution, R is a mineral compound which is a potassium, calcium or antimony containing mineral compound and wherein x is 4, 5, 7, 15 or 30.